



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Quali-Tech Products, Inc.;

Bambermycins; Pyrantel; Tylosin; Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of four new animal drug applications (NADAs), held by Quali-Tech Products, Inc., at the sponsor's request because the products are no longer manufactured or marketed.

DATES: The rule is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843, david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Quali-Tech Products, Inc., has requested that FDA withdraw approval of the following four NADAs because the products, used to manufacture Type C medicated feeds, are no longer manufactured or marketed: NADA 097-980 for Quali-Tech TYLAN-10 (tylosin phosphate) Premix, NADA 118-815 for Q.T. BAN-TECH (pyrantel

tartrate), NADA 132-705 for FLAVOMYCIN (bambermycins), and NADA 133-335 for STAFAC (virginiamycin) Swine Pak 10.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADAs 097-980, 118-815, 132-705, and 133-335, and all supplements and amendments thereto, is withdrawn. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Quali-Tech Products, Inc., will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for this firm.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entry for "Quali-Tech Products, Inc."; and in the table in paragraph (c)(2), remove the entry for "016968".

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. In § 558.95, revise paragraphs (a), (d)(1), (d)(2), (d)(3), (d)(4)(i), and (d)(4)(ii) to read as follows:

§ 558.95 Bambermycins.

(a) Approvals. See sponsors in § 510.600(c) of this chapter for use of Type A medicated articles as in paragraph (d) of this section:

(1) No. 016592: 2, 4, and 10 grams per pound for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) Nos. 012286 and 017790: 2 grams for use as in paragraph (d)(2) of this section and 0.4 and 2 grams per pound for use as in paragraph (d)(3).

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(d) * * *

(1) Chickens. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2	Broiler chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	016592
(ii) [Reserved]			

(2) Turkeys. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2	Growing turkeys: For improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592, 017790.
(ii) 2	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592, 017790.

(3) Swine. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Growing-finishing swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	012286, 016592, 017790.
(ii) 2 to 4	Growing-finishing swine: For increased rate of weight.	Feed continuously as the sole ration.	012286, 016592, 017790.

(4) Cattle. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 4	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 10 to 20 milligrams per head per day.	016592
(ii) 2 to 40	Pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.	Feed continuously at a rate of 10 to 40 milligrams per head per day in at least 1 pound and not more than 10 pounds of feed. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.	016592

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§ 558.485 [Amended]

5. In paragraph (b)(3) of § 558.485, remove "Nos. 016968, and 017790" and in its place add "No. 017790".

§ 558.625 [Amended]

6. In § 558.625, remove and reserve paragraph (b)(14).

§ 558.635 [Amended]

7. In paragraph (a)(2) of § 558.635, remove "046573, 016968, and 017790" and in its place add "046573 and 017790".

Dated: August 20, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2013-20616 Filed 08/22/2013 at 8:45 am; Publication Date: 08/23/2013]